REMARKS/ARGUMENTS

Information Disclosure Statement Dated June 8, 2005

The Examiner is respectfully requested to return to the undersigned a copy of sheet 2 of 2 of the Form PTO/SB/08A dated June 8, 2005 with an indication thereon that application Serial No. 10/524,996 was considered and made of record.

Claim Amendments

Claims 11 and 14 were each amended to recite "and a pharmaceutically acceptable carrier." This amendment is supported in the present specification on page 3, first paragraph, the paragraph bridging pages 7 to 8 and in the Examples beginning on page 8.

Rejection Under 35 USC 103

Claims 11 and 14 were rejected under 35 USC 103 as being unpatentable over Dean et al. (USP 6,166,073) in view of Patent Abstract of Japan and Hellberg et al. (USP 6,646,001) for the reasons set forth on page 2 of the Office Action.

The "Patent Abstract of Japan" is JP 62-277323 (see page 4, lines 15 to 17 of applicants' AMENDMENT UNDER 37 CFR 1.116 filed April 12, 2010).

Claims 11 and 14 were allowed in the previous Office Action of May 25, 2010, i.e., claims 11 and 14 were considered by the Examiner to be patentable over Dean et al. in view of the Patent Abstract of Japan and Hellberg et al.

On page 2 of the Office Action, it was stated that upon further review, claims 11 and 14 were considered not to be in condition for allowance for the following reasons:

> "The examiner had relied on table a and Table b for determining the allowability of claims 11 and 14. However, upon further consideration it is the examiner's position that Table a and b contain other components such as, crystalline sodium dihydrogen phosphate, sodium chloride, diluted hydrochloric acid, sodium hydroxide and purified water at certain concentrations. However, the claims of the instant application do not contain such components. Therefore, it is not clear that without the addition of the above ingredients BAK-C12 in combination with latanoprost as claimed in the instant application would produce a colorless and transparent composition."

Applicants respectfully submit that components such as crystalline sodium dihydrogenphosphate, sodium chloride, hydrochloric acid and purified water are "pharmaceutically acceptable carriers" and therefore are within the scope of applicants' present claims.

In the above quoted excerpt from the Office Action, Table a and Table b appear to refer respectively to Table (a) and Table (b) on pages 10 and 11, respectively, of applicants' AMENDMENT UNDER 37 CFR 1.116 filed January 23, 2009. Table (a) and Table (b) set forth results included in the DECLARATION UNDER 37 CFR 1.132 of Hiroyuki ASADA dated January 20, 2009. Table (a) and Table (b) are reproduced as follows:

Table (a)

	Comparative formulation A-1	Comparative formulation A-2
Latanoprost	0.005	0.005
Crystalline sodium dihydrogenphosphate	0.2	0.2
Sodium chloride	0.9	0.9
BAK	0.007	0.003
Diluted hydrochloric acid	q.s.	q.s.
Sodium hydroxide	q.s.	q.s.
Purified water	q.s.	q.s.
Appearance	White turbidity	Slightly white turbidity

(Unit in Table: % (W/V), q.s.: quantum sufficient)

Table (b)

	Formulation B-1	Formulation B-2
Latanoprost	0.005	0.005
Crystalline sodium dihydrogenphosphate	0.2	0.2
Sodium chloride	0.9	0.9
BAK-C_{12}	0.007	0.003
Diluted hydrochloric acid	q.s.	q.s.
Sodium hydroxide	q.s.	q.s.
Purified water	q.s.	q.s.
Appearance	Colorless and Transparent	Colorless and transparent

(Units in Table: % (W/V), q.s.: quantum sufficient)

As can be seen from the above, all of the examples in Table (a) and Table (b) contained crystalline sodium dihydrogenphosphate, sodium chloride, diluted hydrochloric acid, sodium hydroxide and purified water in the same amounts. Accordingly, it is clear that the addition of crystalline sodium dihydrogen phosphate, sodium chloride, diluted hydrochloric acid, sodium hydroxide and purified water should not have an effect on the experimental results.

Conventional ophthalmic solutions comprising latanoprost contain 0.01% of BAK (which is defined on page 2 of the present specification) as a preservative, and the

addition of 0.01% or less of BAK to an ophthalmic solution comprising latanoprost causes turbidity due to a change of formulation (see the paragraph bridging pages 3 and 4 of the present specification).

An object of the presently claimed invention is to prevent the turbidity in a solution containing latanoprost. The addition of BAK-C_{12} (as in the presently claimed invention), instead of BAK, results in a clear ophthalmic solution without turbidity and maintains as excellent a preservative effect as that obtained using BAK (see Table 9 on page 28 of the present specification). Although an ophthalmic solution comprising latanoprost may be clear, it may not have a preservative effect. Adding BAK-C_{12} as claimed by applicants provides a preservative effect without causing the turbidity that occurs when using BAK.

Withdrawal of the 35 USC 103 rejection is respectfully requested.

Reconsideration and allowance of the above-identified application are respectfully solicited.

If the Examiner has any comments, questions, objections or recommendations, the Examiner is invited to telephone the undersigned at the telephone number given below for prompt action.

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Respectfully submitted,

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